Branch No. 1 of Biophysics Institute

Assurance of Compliance with Department of Energy Regulations for Protection of Human Research Subjects

Branch No. 1 of Biophysics Institute (FIB-1), hereinafter known as the "institution", hereby gives assurance that it will comply with the Department of Energy (DOE) regulations for the protection of human research subjects (10 CFR 745) and the Russian Federation Law on Public Health Protection July, 22, 1993 (Law RF - 93) as specified below

PART 1

Ethical Principles and Institutional Policies Governing Research Involving Human Subjects

I. Applicability

Except for research exempted or waived under the DOE regulations 10 CFR 745 and Law RF-93, Part 1 of this Assurance applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of whether the research is otherwise subject to federal regulation, if:

A the researchis sponsored by this institution, or

B. the research is conducted by or under the direction of any employee or agent of this institution in connection with institutional responsibilities, or

C. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or

D. the research involves the use of this institution's nonpublic information to identify or contact human research subjects or prospective subjects.

II. Ethical Principles

This institution is guided by the ethical principles regarding all research involving human as subjects as set forth in the report of the National Commission for the Protection of Human Subjectsof Biomedicaland BehavioraResearchentitled, EthicalPrinciplesand Guidelines for the Protection of Human Subjects of Research (the "Belmont Report") and Law RF-93 and as specified below.

A. This institution recognizes the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice as stated in the Belmont Report and Law RF-93 and will apply these principles in all research covered by this Assurance.

B. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects

III. Policies

A. This institutions acknowledges that it and its investigators bear full responsibility for the performance of all research covered by this Assurance, including full responsibility for complying with Federal, state, and local laws as they may relate to such research.

B. This institution assures that before human subjects are involved in research, proper consideration will be given to:

(1) the risks to the subjects,
(2) the anticipated benefits to the subjects and others,
(3) the importance of the knowledge that may reasonably be expected to result,
(4) the informed consent process to be employed,
(5) the provisions to protect the privacy of subjects, and
(6) the additional safeguard for vulnerable populations

C. This institution recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or under influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

D. This institution encourages and promotes constructive communication among the institutional officials, research administrators, department heads, research investigators, clinical care staff, human subjects, and all other relevant parties as means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects

E. This institution will exercise appropriate administrative overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

PART 2

IRB, Institution, and Investigator Compliance with 10 CFR 45 and Law RF - 93

I. Applicability

Part 2 of this Assurance applies to the following research projects which are conducted or sponsored by this institution and supported by the Department of Energy.

Project Title: Feasibility Assessment of Biodosimetry and Molecular Epidemiology Studies Among Mayak PA Workers
DOE Project No: 03-98EH98030
Co-Principal Investigators: Nadezhda D. Okladnikova, Branch No. 1 of Biophysics Institute,
William L. Bigbee, Richard D. Day, University of Pittsburgh

II. Institutional Responsibilities

A. This institution has complied and will continue to comply with the requirements of 10 CFR 745 and Law RF - 93 as specified below.

B. In accordance with the compositional and quorum requirements, the Institutional Review Board (IRB) designated in Part 3 and in the attached roster is responsible for the initial and continuing review of these projects.

C. This institution has provided and will continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and record keeping duties.

D. In addition to the review and approval of the IRB, this institution has reviewed and sponsors the projects referenced above.

III. IRB Review

A. The IRB shall review, and have the authority to approve, require modification in, or disapprove this research activity or proposed changes in it before human subjects may be involved.

B. The convened IRB reviewed and approved the above project.

C. The IRB determined, in accordance with the criteria found at 10 CFR 745 and Law RF-93, that protections for human research subjects are adequate.

D. The IRB has the authority to suspend or terminate approval of the above referenced research in accordance with 10 CFR 745 and Law RF-93 for (1) non-compliance with 10 CFR 745 and Law RF-93, and this Assurance document or the IRB's requirements, and (2) for elimination of unexpected serious harm to subjects.

E The IRB has determined that legally effective informed consent [copy of document must be attached unless specified otherwise by OPRR] will be obtained in manner and method which meets the requirements of 10 CFR 745 and Law RF - 93

F Certification of IRB approval, at least annually, shall be submitted to the DOE Office that issued the award, as a conditions for received of funds for a non-competing continuation and/or additional involvement of human subjects

G Continuing reviews by the IRB shall be conducted at intervals appropriate to the degree of risk, but less than once per year *The IRB may be called into an interim review* session by the Chairperson at the request of any IRB member or Institutional Official to consider any matter concerned with the rights and welfare of any subjects

H. The IRB shall prepare and maintain adequate documentation of its activities in accordance with 10 CFR 745 and Law RF - 93

I The IRB shall report promptly to institutional officials and the Office for Protection from Research Risks (OPRR):

(1) any serious or continuing noncompliance by investigators with the requirements of the IRB,

(2) any suspension or termination of IRB approval,

(3) any unanticipated problems or injuries involving risks to subjects or others, and

(4) any changes in this research activity which are reviewed and approved by the IRB

J Where appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children as required under Subparts B , C , and D of 45 CFR 46.

K The IRB will comply fully with the requirements of all applicable Federal policies and guidelines, including those concerning notification of sero-positively, counseling, and confidentiality of subjects.

IV *Research Investigator Reporting Responsibilities*

A. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance and 10 CFR 745 and Law RF - 93

B Research investigators shall report promptly to the IRB proposed changes in this research activity and the changes shall not be initiated without *IRB review and approval* except where necessary to eliminate apparent immediate hazards to the subjects [illegible] Principal investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others.

PART 3

Certification of IRB Approval and Institutional Endorsement

Project Title: Feasibility Assessment of Radiobiology and Molecular Epidemiology Studies Among Mayak PA Workers
DOE Project No.: CC 98EH98030
Co-Principal Investigators: Nadezhda D. Okladnikova, Branch No. 1 of Biophysics Institute
William L. Bigbee, Richard D. Day, University of Pittsburgh

Date of IRB Approval: October 1, 1998
Date of Next Scheduled IRB Review: February, 1999

The officials signing below assure that the research activities/project referenced above was reviewed and approved on the date indicated and that the project will be conducted in accordance with the requirements of Part 745 Title 10 CFR of the Code of Federal Regulations, the Russian Federation Law on Public Health Protection, July 22, 1993, and the Assurance attached. A dated roster listing the current membership of the designated IRB is attached.

1. Authorized Official of the Institution Providing this Assurance

Signature ______ Date 14.10.98

Name and Title: Sergey A. Romanov, Director of FIB-1
Address: FIB-1, Ozyorskoe st. 19, Ozyorsk, 456780, RUSSIA
Telephone: 351 71 [illegible] FAX: [illegible]

2. Authorized Official of the Institution with the IRB
(include only if different from the institution above)

This institution authorizes the designation of its IRB for review of the project referenced in this Assurance.

Signature ______ Date 13.10.98

Name and Title: Eduard R. Lyubchansky, DSc, [illegible]

Address: FIB-1, Ozyorskoe st. 19, Ozyorsk, 456780, RUSSIA
Telephone: 351 71 71 806 FAX: [illegible]

1. IRB Chairperson
Must be completed in all cases (see [illegible])

Signature ____________ Date 1.10.98

Name and Title Vladimir A. Sherkunov, DM, Major physician [illegible]

Address: HB 1, Ozerskoe st. 19, Ozyorsk, 456780, Russia
Telephone 351-71-66-743 FAX [illegible]

2. Responsible Project Investigator or Director at Institution/Cooperating Institution

I have attached copies of all OPRR required and [illegible] Informed Consent Documents to be used in this project

Signature N Okladnikova Date 1.10.98

Name and Title Nadezhda D. Okladnikova, DM, Chief of Clinical Department

Address: HB 1, Ozerskoe st. 19, Ozyorsk, 456780, Russia
Telephone 351-71 65-487 FAX [illegible]

[illegible]

[illegible]

RUSSIA
Telephone [illegible]
FAX [illegible]

- SPACE BELOW FOR DOE -

All parts of this Assurance are in compliance with the requirements of Part 745, Title 10 CFR of the Code of Federal Regulations.

DOE Approving Official

Signature Susan L Rose **Date:** 11/30/98

Name: Susan L. Rose, U.S. Department of Energy
Address: SC-72/Room G-143, 19901 Germantown Road, Germantown, MD 20874-1290
Telephone: (301) 903-4731
FAX: (301) 903-8521

ASSURANCE NUMBERS- EH-699BIG

Signature Date: 11/24/98

Name: Eleanor Melamed, U.S. Department of Energy
Address: EH-64/270CC, 19901 Germantown Road, Germantown, MD 20874-1290
Telephone: (301) 903-8044
FAX: (301) 903-1413